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| EXAMINER | |
|---|---|
| WOLF, MEGAN YARNALL | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3738 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,338 | LERF, RETO | |
| | Examiner | Art Unit | |
| | Megan Wolf | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *040909*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. The declaration under 37 CFR 1.132 filed 4/9/09 is insufficient to overcome the rejection of claims 1, 2, and 4-46 based upon the rejection under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723, Shimamune 5,034,186 in view of Steinemann, Rowe et al. 4,542,539 in view of Steinemann, Pilliar in view of Steinemann in further view of Pilliar 4,206,516, Rowe in view of Steinemann in view of Landry 2004/0030387, and Pilliar '638 in view of Steinemann in further view of Landry, as set forth in the last Office action because: The declaration fails to set forth sufficient evidence that the etching process taught by Steinemann that creates a microstructure or roughness on an implant contact surface would severely damage or destroy the surface of the primary references including Pilliar, Shimamune, and Rowe. The declaration states that the acid bath of Steinemann "would dramatically attack and damage any surface similar to those described in any of Pilliar, Shimamune, or Rowe irrespective of whether this surface was plasma spray deposited or sintered", however, the application's specification discloses that an acid bath is successfully used on porous surfaces to create a microstructure and does not attack or damage the porous surface. The specification does not specifically disclose how the acid bath of the invention differs from the acid bath of Steinemann or how the acid bath can be controlled to produce fine etching pits without causing damage and therefore without specific evidence or data comparing the invention with the acid bath of Steinemann, simply stating that the method taught by Steinemann would destroy the

porous surfaces of the primary reference is not sufficient and does not overcome the previous rejections. It is further noted that the method of Steinemann is applied to a contact surface of a porous surface of an implant to create a roughness on the contact surface of the porous surface (col.3, ll.2-5, ll.19-24; clm.1). In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

***Response to Arguments***

2. Applicant's arguments filed 4/9/09 have been fully considered but they are not persuasive. Applicant argues that one of ordinary skill in the art would not combine Pilliar or Shimamune or Rowe with Steinemann because the primary references promotes large open pores while Steinemann promotes a small roughening and that because each idea promotes a different scale of roughening, the limited independent success of each idea was previously considered contradictory. The examiner disagrees with this analysis. As discussed in the previous office action, these two features are distinct and do not teach away from each other. For example, the pores of Pilliar are used for the purpose of allowing bone to grow into the implant. It is very well known in the art that pores must be greater than about 100 microns for this to occur. The pits of Steinemann, which are preferably 2 microns, are used to create a rough surface which bone may adhere to. The pits of Steinemann are not intended to allow bone to grow into the implant and do not replace the pores in the implant surface, in fact Steinemann very clearly discloses that the pits are applied to a *porous surface* (col.3, ll.2-5, ll.19-24; clm.1). Applicants continue to compare the pores to the pits, but the two features are

distinct throughout the art and even in the invention. For example applicant argues that Steinemann addressed the large-pore teachniques of Pilliar, but this is not the case. Steinemann teaches that the *roughness (pits)* should be about 2 microns which does not teach away from the *pore size* taught by Pilliar which should "exceed about 50 microns". Regarding the argument that Steinemann teaches away from a vacuum plasma spraying process, Steinemann is referring to a process for creating a roughness by this method and not an open-pored porosity. Regarding the argument that the pores of Steinemann are actually pits, Steinemann specifically states in col. 3, lines 3-5, "the implant being provided with a **porous** surface which is to come in contact with the bone, wherein the contact surface is provided with micro-roughness having fine **pitting** superimposed thereon" (emphasis added). There is no indication in the reference that the pores of the porous surface are pits as applicants have alleged. Applicant further argues that the acid etch used by Steinemann would to a degree destroy the surface of Pilliar, Shimamune and Rowe. However, there has not been sufficient proof of this as discussed above in the response to amendments.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 6-8, 10-12, 15-20, 22, 26-31, 37, 40-42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723.

Re claims 1, 2, and 37, Pilliar teaches the invention substantially as claimed including an open-pored surface layer comprising biocompatible metal with particles having a particles size in a range of approximately 50-800 microns (col.4, l.39) with a thickness in a range from 0.1mm to 2.5mm inclusive (col.4, ll.21-33) and the porosity of the open-pored surface layer in a range from 20% to 80% (col.11, ll.1-2). However, Pilliar does not disclose that the open pored layer further comprises pits as roughening having a diameter in the range of 0.1-2.5 microns.

Steinemann teaches a porous metallic implant, in the same field of endeavor, comprising a porous surface with a surface roughness of 2μm or less (col.3, ll.1-5 and 23-25; clm.1), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during its use (col.2, ll.45-50).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porous surface disclosed by Pilliar in view of the sub-micrometer surface roughness taught by Steinemann in order to improve adhesion of the mating bone with the implant along the contact surface and to quickly form a strong and durable bond as taught by Steinemann, col.3, ll.20-23. Note that the process by

which the product is produced is not germane to the issue of patentability in an apparatus claim.

Re claims 6 and 40, see Pilliar col.2, ll.65-67 and Steinemann claim 5.

Re claim 7, see Pilliar col.8, ll.33-36.

Re claim 8, Pilliar discloses the invention substantially as claimed including a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant, to produce an implant surface comprising an open-pored structure with a porosity in a range of between about 20% and 85% (col.8, ll.9-38; col.11, ll.1-2). However, Pilliar does not disclose producing a surface micro-structure on the open-pored structure.

Steinemann teaches a method of making a porous metallic implant, in the same field of endeavor, comprising producing a surface micro-structure on a porous structure (col.3, ll.1-5 and 23-25; clm.1), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a micro-structure on the porous surface disclosed by Pilliar as taught by Steinemann in order to improve adhesion of the mating bone with the implant along the contact surface and to quickly form a strong and durable bond.

Re claims 10 and 11, see Pilliar col.8, ll.57-60.

Re claim 12, see Pilliar col.7, ll.29-32.

Re claim 15, see Pilliar col.7, ll.37-40.

Re claim 16, see Pilliar col.7, ll.49-51.

Re claim 17, see Pilliar col.4, ll.38-40.

Re claim 18, see Pilliar col.4, ll.21-33.

Re claim 19, see Pilliar col.7, l.47.

Re claim 20, see Pilliar col.2, ll.65-67.

Re claims 22 and 31, see Steinemann clm.1.

Re claims 26-28, see Pilliar col.5, ll.38-40 for the intended use of the device

Re claims 29 and 30, see Pilliar col.8, ll.9-38.

Re claims 41, 42, and 44, Pilliar in view of Steinemann discloses the invention substantially as claimed, but does not specifically disclose that the average diameter of the pores is 300 microns. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Because Pilliar discloses that the pores may be about 200 microns in diameter, it would have been obvious to try varying the pore size to achieve the optimal bone ingrowth to arrive at a specific average pore size.

Re claim 45, as Steinemann discloses a surface micro-structure on a porous surface, the porous surface is preserved as claimed.

5. Claims 8, 11-14, 17, 18, 20, 22, 26-31, 42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186 in view of Steinemann et al. 5,456,723.

Re claim 8, Shimamune teaches a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant to produce an implant surface (col.1, l.59-col.2, l.2, and col.4, ll.55-57) comprising an open pored structure with a porosity in a range between about 20% and 85% (col.2, ll.64-66). However, Shimamune does not disclose the step of producing a surface micro-structure on the open-pored structure.

Steinemann teaches a method of making a porous metallic implant, in the same field of endeavor, comprising producing a surface micro-structure on a porous structure (col.3, ll.1-5 and 23-25; clm.1), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a micro-structure on the porous surface disclosed by Shimamune as taught by Steinemann in order to improve adhesion of the mating bone with the implant along the contact surface and to quickly form a strong and durable bond.

Re claim 11, Shimamune further teaches a method wherein the at least one layer applied to the virgin surface of the implant is sintered (col.3, l.9).

Re claim 12, Shimamune further teaches a method wherein materials are selected from the group consisting of binders, and sintering adjuvants (col.2, l.67).

Re claim 13, Shimamune further teaches a method wherein as sintering adjuvant there is used a sintering adjuvant metal (col.2, ll.27-28) which, together with the biocompatible metal or alloy thereof, forms a low-melting eutectic (col.2, ll.28-44).

Re claim 14, Shimamune further teaches a method wherein sintering is carried out in vacuo (col.1, ll.66-68).

Re claims 17 and 20, see Shimamune col.2, ll.54-58.

Re claim 18, see Shimamune col.4, ll.29-31.

Re claims 22 and 31, see Steinemann clm.1.

Re claims 26-28, see Shimamune col.4, l.57.

Re claims 29, 30, and 42, see Shimamune col.2, ll.64-66.

Re claim 45, as Steinemann discloses a surface micro-structure on a porous surface, the porous surface is preserved as claimed.

6. Claims 8, 9, 33-35, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. 4,542,539 in view of Steinemann et al. 5,456,723. Rowe discloses the invention substantially as claimed including applying at least one layer of a biocompatible metal or an alloy thereof comprising particles having a particle size in a range of about 50-800 microns (col.7, ll.65-66) to a virgin surface of an implant to produce an open-pored implant surface (figs. 1-4) wherein the open-pored implant surface is produced by a plasma spraying method (col.5, ll.45-48) such that an open-pored structure is generally maintained (figs.1-3) and the average pore diameter is 300 microns (col.5, ll.38-40). However, Rowe does not specifically disclose the step of producing a micro-structure on the open-pored implant surface.

Steinemann teaches a method of making a porous metallic implant, in the same field of endeavor, comprising producing a surface micro-structure on a porous structure (col.3, ll.1-5 and 23-25; clm.1), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a micro-structure on the porous surface disclosed by Rowe as taught by Steinemann in order to improve adhesion of the mating bone with the implant along the contact surface and to quickly form a strong and durable bond.

Re claims 45 and 46, as Steinemann discloses a surface micro-structure on a porous surface, the porous surface is preserved as claimed.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723, as applied to claim 8 above, and further in view of Pilliar 4,206,516. Pilliar '638 in view of Steinemann teaches the invention substantially as claimed but does not teach a method wherein the biocompatible metal is used in the form of a metal hydride powder.

Pilliar '516 teaches a method of making a coating, in the same field of endeavor, wherein the biocompatible metal is used in the form of a metal hydride powder (col.2, ll.46-49), for the purpose of providing a thermally decomposable compound (col.2, ll.50-51).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the biocompatible metal of Pilliar '638 as modified by Steinemann with the metal hydride powder taught by Pilliar '516 in order to provide a thermally decomposable compound.

8. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. 4,542,539 in view of Steinemann et al. 5,456,723 as applied to claim 33 above, and further in view of Landry 2004/0030387. Rowe in view of Steinemann discloses the invention substantially as claimed. However, Rowe in view of Steinemann does not disclose that the surface microstructure comprises a biocompatible metal applied as particles having a particle size in a range from 0.01-5 microns.

Landry teaches an implant, in the same field of endeavor, wherein the bone-contacting surface may be roughened for the purpose of promoting osteointegration. Landry further teaches that the surface may be roughened by etching or embedding particles in the surface (pars.15, 91).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the step of embedding particles in the implant surface as taught by Landry for the etching step taught by Steinemann as they are taught by Landry to be obvious equivalents of one another for the purpose of providing roughness to an implant surface to promote osteointegration. Note that because Steinemann discloses that the roughness should be about 2 microns, it would have been further obvious to use particles this size to achieve the same resultant roughness.

9. Claims 4, 5, 23-25, 32, 38, and 39, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723, as applied to claims 1, 8, and 37 above, and further in view of Landry 2004/0030387. Pilliar in view of Steinemann discloses the invention substantially as claimed and as discussed above. However, Pilliar in view of Steinemann does not disclose that the surface microstructure is created by application of fine biocompatible particles having a particle size in a range from 0.01-5 microns.

Landry teaches an implant, in the same field of endeavor, wherein the bone-contacting surface may be roughened for the purpose of promoting osteointegration. Landry further teaches that the surface may be roughened by etching or embedding particles in the surface (pars.15, 91).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the step of embedding particles in the implant surface as taught by Landry for the etching step taught by Steinemann as they are taught by Landry to be obvious equivalents of one another for the purpose of providing roughness to an implant surface to promote osteointegration. Note that because Steinemann discloses that the roughness should be about 2 microns, it would have been further obvious to use particles this size to achieve the same resultant roughness.

Re claim 24, Pilliar teaches application of fine biocompatible particles applied by a sol-gel method using a binder (col.7, ll.29-32). As Landry teaches that the surface may be roughened by attaching particles to the surface, it would have been obvious to

use the sol-gel method of attaching biocompatible particles taught by Pilliar to do so as this is a well known technique.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738